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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/180,209	12/22/99	KARPUSAS M	B189

HM12/0926

BIOGEN INC
14 CAMBRIDGE CENTER
CAMBRIDGE MA 02142

EXAMINER	
OGIHARA,N	
ART UNIT	**PAPER NUMBER**
1631	15

DATE MAILED: 09/26/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/180,209	KARPUSAS ET AL.	
	Examiner	Art Unit	
	Nancy Ogihara	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) *1-11 and 13-37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-37* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been:

1.☐ received.

2.☐ received in Application No. (Series Code / Serial Number) _____ .

3.☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

The numbering of claims has been changed in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 13-38 (as shown on the amended claim sheet) have been renumbered 12-37, respectively. The restriction requirement, as set forth in the previous Office Action, reflect the renumbered claims.

Claims 1-37 are pending in the instant application. Applicant's election with traverse of Group V, claim 12, in the paper filed 9/8/00 is acknowledged.

Applicant argues that the claims of Group V should be rejoined with claims of Group II as a search on the subject matter of Group II will necessarily involve a search of the subject matter of Group V.

Applicant's arguments have been fully considered, but they are not persuasive for the following reasons: As set forth in the restriction requirement, Group II possesses the inventive concept of being drawn to a computer readable medium, and Group V possesses the inventive concept of being drawn to a method of using the structural coordinates of CD40 ligand for structure determination. A computer readable medium of Group II does not require the storage or use of structural coordinates of a CD40 ligand for structure determination.

Therefore, the requirement is still deemed proper and is therefore made FINAL.

Claims 1-11 and 13-37 are withdrawn from further consideration as being drawn to a non-elected invention. Claim 12 is pending and under examination as elected.

Oath

The oath is missing the citizenship of Inventor Singh. The oath is also missing post office addresses for all of the inventors. Appropriate correction is required.

Abstract

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Sequence Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 since no submission of a computer readable form of the sequences (shown in Figure 5) has been submitted. Applicant is reminded that no SEQ ID NO's are required to be amended into figures containing sequences. Applicants are given the same response time regarding this failure to comply as that set forth in this office action.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 12 is rejected under 35 U.S.C. §101 because the claimed invention is directed to non-statutory subject matter and is therefore not patentable. See MPEP §2106 which states that

> "Descriptive material can be characterized as either "functional descriptive material" or "nonfunctional descriptive material." In this context, "functional descriptive material" consists of data structures and computer programs which impart functionality when encoded on a computer-readable medium...."Nonfunctional descriptive material" includes but is not limited to music, literary works and a compilation or mere arrangement of data.
>
> "When nonfunctional descriptive material is recorded on some computer-readable medium, it is not structurally and functionally interrelated to the medium but is merely carried by the medium. Merely claiming nonfunctional descriptive material stored in a computer-readable medium does not make it statutory. Such a result would exalt form over substance."

In the claim, the computer-readable medium is merely storing recorded data (i.e. structural coordinates) with the intent of being used for structure determination. The invention appears to be the coordinates, *per se*, which are deemed non-statutory, as the coordinates are not functionally interrelated to the computer-readable medium. Therefore, the claim is considered non-statutory subject matter.

Claim Rejections - 35 USC § 112

Claim 12 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a computer readable data storage medium capable of displaying a three dimensional representation of a crystal or model of residues 116-261 of human CD40 ligand, for does not reasonably provide enablement for non-human CD40 ligands, molecular complexes of CD40 ligand, or full-length CD40 ligand, and fails to enable the scope of the claims.

The claims are directed to a computer readable data storage medium capable of displaying a three dimensional representation of a crystal or model or molecular complex of human CD40 ligand. The specification discloses only the crystallization and structure determination of human CD40 ligand containing residues 116-261 (see Example 1, page 33). The disclosed co-crystal structure is not necessarily representative of the native full-length protein structure which also contains a transmembrane region and an N-terminal intracellular region (see page 2, 1st full paragraph). The disclosed computer readable data storage medium does not take into account the N-terminal 115 amino acid residues of CD40 ligand which have an unspecified structure/function role on the conformation and binding of associating compounds that form complexes. Furthermore, specification does not disclose representative examples of ligand bound complexes or hetero-complex forms of the protein, or the possible domain movements that may occur upon binding of an associating compound (i.e. induced fit type movements). Furthermore still, only the human CD40 ligand protein has been disclosed, and structures from other species have not been disclosed. Although a certain amount of sequence similarity may exist between the human CD40 ligand and those from other species, one of skill in the art could not predictably display on a computer readable data storage medium representative structures of CD40 ligands, other than residues 116-261 of the human protein.

Because of the above mentioned uncertainties, a computer readable data storage medium capable of displaying a three dimensional representation of a crystal or model or molecular complex of

human CD40 ligand is unpredictable and would require undue experimentation as the claim does not take into account the structural differences between the disclosed structure and the full length protein, conformational changes between the unbound and a complex, or the sequence differences between human and other species. Therefore, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with claims.

Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 is vague and indefinite in the recitation of the abbreviated term "CD40L." The full name of CD40L should be completely spelled out at its first appearance and not abbreviated. Appropriate correction is required.

Claim 12 is vague and indefinite in the recitation of the terms "Lys142," "Arg203," "Arg207," and "Tyr145." The numbering of a residue within a sequence is relative to a SEQ ID or a designated sequence, and by itself, does not designate a unique residue because of the non-uniformity in sequence numbering from one protein to another within a set of related sequences.

Claim 12 is vague and indefinite in the recitation of the term "binding site." The metes and bounds are unclear as it is not certain what is meant by binding. For example, the "binding site" can be interpreted as a ligand binding site, an inhibitor binding site, a co-activator binding site, a solvent binding site, etc...

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 12 is rejected under 35 U.S.C. 102(b) as being anticipated by Peitsch *et al.* (IDS document: International Immunology, Vol. 5(2), pp. 233-238, 1993).

Peitsch *et al* disclose of modeling the three-dimensional structure of CD40L using the molecular modeling package ProMod (see page 234, left and right columns). Such computational

modeling necessarily requires a machine readable data storage medium comprising a data storage material (i.e. a hard drive, memory, RAM) encoded with machine readable data (i.e. PDB coordinates) which, when read by an appropriate machine (i.e. UNIX or VMS workstation), displays a three dimensional representation of a crystal of a molecule or fragment of CD40L (see Figure 2) having a binding site comprising residues Lys143, Arg203, Arg207, and Tyr145.

Given the above, Peitsch *et al.* meet the limitations of the claims.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy Ogihara whose telephone number is (703) 308-9363. The examiner can be reached Monday-Friday from 8:30-5:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Michael Woodward can be reached at (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center receptionist, whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1631 by facsimile transmission. Papers should be faxed to Group 1631 via the PTO Fax Center located in Crystal Park I. The faxing of such papers must conform with the notice published in the Official 1Gazette 1096 OG 30 (November 15, 1989). The CMI Fax Center number is (703) 308-4242.

Nancy Ogihara
September 19, 2000

ARDIN H. MARSCHEL
PRIMARY EXAMINER